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JUL 2 4 2013

Official Contact: Renee Thornborough – Director QA/RA

Proprietary or Trade Name: Model HEM-6131

Common/Usual Name: Noninvasive blood pressure measurement system.

Classification Name/Code: DXN – Noninvasive blood pressure measurement system.

21CFR 870.1130
Class II

Device: Model HEM-6131

Note that the device is sometimes referred to as the HEM-6131-LA in this submission, this is just an Omron internal name the HEM-6131 and HEM-6131-LA are identical

Predicate Device: Omron – HEM-609N (HEM-6001-Z) - K042505

Device Description:
The device is an automatic non-invasive blood pressure system. The device is battery powered by 2 "AAA" batteries, there is no connection to external power. The device inflates a wrist cuff with an integral pump, then deflates the cuff via an electronically controllable valve. During inflation the cuff pressure is monitored and pulse waveform data is extracted. The extracted pulse waveform data is then analyzed by software which determines pulse rate, as well as systolic and diastolic pressure. The algorithm used to determine pulse rate, systolic and diastolic pressure is identical to the predicate.

The device has a memory function that automatically stores up to 60 of the latest measurements. It can also display an average of the last three values

The device also detects the appearance of irregular heartbeats during measurement.

Intended User
Home user

Patient Population

This device is intended for use on adults.

Indications for Use:
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm).

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environment of Use:
Home

Contraindications:
There are no known contraindications.

Predicate Device Comparison:

The HEM-6131was compared to the predicate HEM-609N (k042505) in the device comparison table below.

Device Comparison

	Omron HEM-6131	Omron HEM-609N 510(k) K042505	Comment
Indications for Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Identical
Patient Population	Adult	Adult	Identical
Environment of Use	Home	Home	Identical
Prescriptive	OTC	No	Identical
Patient Connection	Yes via cuff	Yes via cuff	Identical
Technology	Oscillometric	Oscillometric	Identical
Measurement range	Pressure: 0-299 mmHg Pulse rate: 40 to 180 bpm	Pressure: 0-299 mmHg Pulse rate: 40 to 180 bpm	Identical
Accuracy or pressure indicator	+/- 3 mmHg or 2% of reading	+/-3 mmHg	Similar
Pressure sensor	Piezo resistance sensor	Silicone capacitive sensor	Similar, identical function
Accuracy Pulse Rate	+/-5%	+/-5%	Identical
Inflation Method	Electric pump	Electric pump	Identical
Deflation Method	Internal valve	Internal valve	Identical
Display Type	LCD	LCD	Identical
Irregular pulse detection	Yes	Yes	Identical
Power Source	AAA batteries	AAA batteries	Identical
Operating Conditions	Temperature: 10° to 40° C Humidity: 15 to 85% RH	Temperature: 10° to 40° C Humidity: 30 to 85% RH	Similar
Storage Conditions	Temperature: -20° to 60° C Humidity: 10 to 95% RH	Temperature: -20° to +60 °C Humidity: 10 to 95% RH	Identical
Dimensions	78(W) x 60(D) x 21(H) mm	70(W) x 54(D) x 37(H) mm	Similar
Weight	Approximately 101g	110g	Similar

Differences Between Other Legally Marketed Predicate Devices:
The Omron HEM-6131 is viewed as substantially equivalent to the predicate device because: The HEM-6131 uses the exact same technology and has identical indications for use. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications –
The indications for use measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
Discussion – These indications are identical to the predicate Omron HEM-609N (k042505).

Prescriptive – The HEM-6131 and predicate are both OTC.

Design and Technology – The HEM-6131 has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The HEM-6131 has equivalent specifications of performance as the predicate.

Compliance with standards – The HEM-6131 and predicate device declare compliance with SP10, IEC 60601-1 and IEC 60601-1-2.

Materials –
The patient contacting materials of the cuffs has been tested in accordance with ISO 10993-1 and FDA Guidance. The tests included Cytotoxicity, Sensitization, and Intracutaneous Reactivity.

Patient Population –
The HEM-6131 and predicate are indicated for adults

Non-Clinical Testing Summary:

We have performed bench tests and found that the HEM-6131 met all requirements specifications and standards requirements and were found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing
- Testing for compliance to IEC 60601-1

- Testing for compliance to IEC 60601-1-2
- Testing for compliance to AAMI SP10
- Comparative Testing to the Predicate

Clinical Testing Summary:
Testing to insure clinical accuracy of the device in accordance with ANSI/AAMI/ISO 81060-2 as documented in **Section 20.**
Eighty five patients (36 males and 49 females) were recruited for the study.
Standard auscultation method was used as the reference blood pressure (BP) measuring in the left upper arm. BP measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in AAMI.

Substantial Equivalence Conclusion
Omron maintains that the HEM-6131 is substantially equivalent to the predicate HEM-609N (k042505) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 24, 2013

Omron Healthcare, Inc.
c/o Mr. Paul Dryden
Consultant
24301 Woodsage Drive
Bonita Springs, FL 34134 US

Re: K131742
Trade/Device Name: Hem-6131
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 11, 2013
Received: June 13, 2013

Dear Mr. Paul Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K131742

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: **Omron HEM-6131**

Indications for Use:

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm).

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environments of Use: Home
Patient Population: Adult

Prescription Use (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use _XX_** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.07.24
14:08:08 -04'00'